

13 JUN 1994

PATENTKONTOR

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

ONSAGERS Patentkontor AS
P.O. Box 265 Sentrum
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NORVEGE

WRITTEN OPINION

(PCT Rule 66)

First noted:

10/8 sm

Date of mailing
(day/month/year)

10. 06. 94

Applicant's or agent's file reference

Fod 1 P 93496 Hv

REPLY DUE

within 3 months/days
from the above date of mailing

International application No.

PCT/NO 93/00136

International filing date (day/month/year)

10/09/1993

Priority date (day/month/year)

14/09/1992

International Patent Classification (IPC) or both national classification and IPC

G01N33/53

Applicant

FODSTAD, Oystein et al

1. This written opinion is the FIRST (first, etc.) drawn up by this International Preliminary Examining Authority.

2. This report contains indications and corresponding pages relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14/01/1995

Name and mailing address of the IPEA/



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Authorized officer

Examiner

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Formalities officer

(incl. extension of time limits)

Telephone No. 2399-8161

Waltraud Hebert

I. Basis of the opinion

1. This opinion has been drawn up on the basis of:

☐ the international application as originally filed.

☒ the description, pages 1-27 _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,

☒ the claims, No. _____, as originally filed,
No. _____, as amended under Article 19,
No. _____, filed with the demand,
No. 1-16 _____, filed with the letter of 14.04.94,

☐ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,

2. The amendments have resulted in the cancellation of: pages: _____
sheets of drawings/figures No.: _____.

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed:

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-16 (YES) _____
	Claims _____
Inventive Step (IS)	Claims 1-16 (NO) _____
	Claims _____
Industrial Applicability (IA)	Claims 1-16 (YES) _____
	Claims _____

2. CITATIONS AND EXPLANATIONS

1. The following document (D) is referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO-A-92 04961

2. The present application satisfies the criterion set forth in Article 33(2) PCT because the subject-matter of Claims 1-16 is new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

- 3.1 However, it seems that the present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matter claimed does not involve an inventive step (Rule 65(1)(2) PCT). Indeed, the object of the present invention is to detect and examine particular target cells in cell suspensions of mixed cell populations, without unspecific binding to normal cells. The solution proposed is to use an insoluble magnetic support, coated with specific antibodies to cell mem-
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brane antigens, to form a complex between the target cells and the magnetic insoluble support. The method is such that a later cleavage between the insoluble support and the target cells is not necessary.

3.2 However, in the relevant prior art D1 it is also mentioned that a separate resuspension of the target cells is avoided and that analytical procedures as quantitative determinations may be performed on the magnetically immobilized colloid (see D1, in particular, page 23). Therefore, the present invention appears to be obvious to the skilled person.

3.3 The Applicant is requested to show advantageous features of the process claimed in the present application over the prior art process which could substantiate inventivity.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The subject-matter of Claim 1 should be identified as "A method for..." instead of "Improved method for...". ✓
2. To meet the requirements of Rule 5.1(a)(ii) PCT, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.
3. The PCT application numbers mentioned in the description should be replaced by the corresponding publicly accessible publication numbers. ✓
4. The terms Tween (page 11, claim 1.4.1) and Dynabeads (pages 19, 21) appear to be registered trade marks and should be identified as such.
5. The Applicant is requested to file amendments by way of replacement pages. He should also take into account the requirements of Rule 66.8 PCT. In particular, fair copies of the amendments should preferably be filed in triplicate.

In order to expedite further examination you are requested to indicate with your reply the locations in the application as originally filed of the passages forming a basis for the amendments.

The attention of the Applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, Article 34(2)(b) PCT.

Any information the Applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply rather than be incorporated into the application, Article 34(2)(b) PCT.